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H. Thomas Anderton, Esq.
Patent Counsel
Genencor International, Inc.
925 Page Mill Road
Palo Alto, CA 94304-1013

[REDACTED] EXAMINER

SLOBODYANSKY, ELIZABETH

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1652

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/075,907	DAVIS ET AL.
	Examiner Elizabeth Slobodyansky	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 18-34,36-68 and 70 is/are pending in the application.
- 4a) Of the above claim(s) 18-34, 46-68, 70 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36-45 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3

- 4) Interview Summary (PTO-413) Paper No(s). 10.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other:

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DETAILED ACTION

Claims 18-34, 36-68 and 70 are pending.

Election/Restriction

Claims 18-34, 46-68 and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups I and III-V, there being no allowable generic or linking claim. Election was made in Paper No. 7 filed April 7, 2003.

Applicant's election of Group II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, Applicants did not indicate the elected species.

In response to a letter of a non-responsive reply mailed June 2, 2003, "Applicants hereby elect the "polypeptide" and elect the invention in Category II, Claims 36-45, drawn to a method of assaying for a preferred enzyme, classified in class 435, subclass 18" (Response to Restriction Requirement filed June 25, 2003). Since said response did not represent the required election of species from "a protease, a cellulase, an amylase, a laccase and a lipase", a telephone call was made to Mr. Thomas Anderton on July 16, 2003 to request an oral election of the species, at what

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time the election of the species of a protease was made without traverse (Interview Summary, Paper No.10, attached herein).

Claim Objections

Claim 36 is objected to because of the following: "swatch" is mistyped on line 7. Appropriate correction is required.

Specification

The instant disclosure contains sequence disclosure that is encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, while the computer readable form (CRF) contains the correct information reading the application data, the paper copy is a copy from the parent case. Applicants are required to submit the paper copy of the Sequence Listing containing the updated application data together with a statement that it is identical to the CRF present in the file. No CRF is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 36-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 36 is drawn to "a method of assaying for a preferred enzyme, said method comprising: a) providing a swatch of material comprising a piece of material and a stain; b) fixing the stain to the material; c) applying an enzyme to the swatch; and d) incubating the swatch and the enzyme.

Therefore, claim 36 recites a genus of proteins, a genus of materials, a genus of stains and a genus of fixation agents. Each of these genera encompasses unlimited number of compounds and materials. Enzymes are an enormous group of proteins both naturally-occurring and man made with totally different structures, effects and utilities. Materials are an enormous group of unrelated materials both naturally-occurring and man made such as different types of textile, ceramic, wood, etc. Fixation agents are a genus of chemically unrelated compounds having different structures, effects and utilities such as hydrogen peroxide, glutaraldehyde, glyoxal, succinaldehyde, etc.

It is apparent that each given stained swatch requires specific genus of enzymes and fixation agents. The specification does not teach the correlation among genera of stains, materials, enzymes and fixation agents.

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Claim 38 limits enzymes to a protease, a cellulase, an amylase, a laccase and a lipase. Each of them encompasses a distinct genus of enzymes. Claim 39 recites a modified hydrolase wherein one or more amino acid residues in the hydrolase are replaced by cysteine residues, wherein the cysteine residues are modified by replacing the thiol hydrogen in said cysteine residues with a substituent group providing a thiol side chain comprising a multiply charged moiety. Hydrolases are a class of enzymes comprising several families of enzymes with different structures, catalytic action and effects. They include several families of enzymes such as proteases. Even a genus of proteases encompasses enzymes with different structures and functions. Claims 39 limits neither the starting unmodified enzyme nor modifications and function.

The specification teaches a chemically modified mutant (CMM) of a protease, *Bacillus lenthus* subtilisin (SBL) obtained by replacement of an amino acid residue with various alkyl and mono-, di- and triammonium groups using methanethiosulfonate (MTS). The specification teaches that said variants can be used in washing blood/milk/ink swatches (pages 26-27).

The specification fails to describe any other representative species of proteases or other enzymes, stains and materials.

However, when, like in the instant case, there is great variation within each genus, one must describe a sufficient variety of species to reflect the variation within the genus. Satisfactory disclosure of a representative number depends on whether one

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of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.

Thus, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 36-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of use of CMM of SBL with a protein stained swatch, does not reasonably provide enablement for a method of use of said CMM with other stains and materials and for a method of use of any enzyme with any stained material and any fixation agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

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the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 36, 37 and 40-45 encompass any enzyme. Claim 38 limits enzymes to a protease, a cellulase, an amylase, a laccase and a lipase. Claim 39 encompasses any hydrolase. The specification does not teach the correlation among a stain, a material, a fixation agent and an enzyme. While the art enables the use of a protease to remove a protein stain from a textile swatch, a lipase to remove oil, an amylase to remove starch, for example, there is no teaching in the art or guidance in the specification as to how to remove a protein stain with a lipase, for example, i.e. how to use an enzyme of any specificity with any stain and material. With regard to claims 41 and 42, there is no guidance as to what enzyme should be used with a given stain or which protease other than subtilisin should be used to remove blood/milk stain. There is no teaching as to what enzyme removes ink. Furthermore, claim 43 comprises fixation of a stain with a cross-linking agent. The specification does not teach a cross-linking agent used for said purposes and does not provide a guidance as to why a stain should be additionally fixed when the purpose of the procedure is its removal. It is clear that each combination of stain and material requires its own pool of enzymes from which the preferred enzyme, i.e. the enzyme having the high performance in removing the given stain from a specific material is chosen. The guidance provided by the specification is at most

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limited to CMMs of SBL and blood/milk stain on a cotton swatch. The art teaches that finding an enzyme useful for removal of a specific stain from a given material is a matter of trial and error.

Thus, searching for an enzyme useful in any application is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

Therefore, one skilled in the art would require guidance beyond that provided in the specification as to how to make an enzyme useful for removal of any stain or fixed stain from any material and how to use a CMM of SBL for removal of stains other than blood/milk on cotton swatches. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, with dependent claims 37-45, is rejected under 35 U.S.C. 112,

second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is drawn to "a method of assaying for a preferred enzyme". It is unclear at what performance the enzyme meant to be "preferred". Claim 36 is incomplete as omitting essential steps such as the step of comparing the degree of removal of the

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stain in the presence and absence of the enzyme, for example. Claim 37 is unclear because there is no definition of the control relative to which the degree is determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 36-38, 40-42, 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Graycar et al.

Graycar et al. (US Patent 6,586,221 B2) teach a wash test that comprises washing a cotton swatch stained with blood/milk/carbon black with detergent comprising different subtilisin variants and comparing performance of said variants (column 21, line 35, through column 22, line 66, Example 6). The stains are fixed on

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cloth swatch since they are present thereon. Therefore, the wash test disclosed by Graycar et al. anticipates claims 36-38, 40-42, 44 and 45.

Claims 36-38, 40, 41, 44 and 45 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Sierkstra et al.

Sierkstra et al. (US Patent 5,837,517) teach a wash test that comprises washing a cotton swatch stained with grass juice with detergent comprising different subtilisin variants and comparing performance of said variants (column 35, line 20, through column 36, line 66, Example 4). The stains are fixed on cloth swatch since they are present thereon. Therefore, the wash test disclosed by Sierkstra et al. anticipates claims 36-38, 40, 41, 44 and 45.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-42, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graycar et al. in view of Bott et al.

The teachings of Graycar et al. are outlined above.

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Claim 36-38, 40-42, 44 and 45 are included in this 103 rejection to the extent that they clearly encompass the methods with the limitations of claim 39, wherein said enzymes are modified hydrolases. The particular embodiment of claim 39 is not anticipated although as discussed above, claims 36-38, 40-42, 44 and 45 also embrace embodiments which are anticipated. Thus, both the 102 and 103 rejections are proper.

Bott et al. (WO 97/37007, form PTO-1449, reference B4) teach a CMM of SBL multimer wherein a residue at position 24 is replaced with cysteine and is attached to the next monomer using MTS. The dimer showed improved performance in the hydrolysis of skim milk or keratin (Example 3, Figures 2 and 3).

It would have been obvious to one of ordinary skill in the art at time the invention was made, to use a CMM disclosed by Bott et al. in a method disclosed by Graycar et al. One of ordinary skill in the art at the time of filing would have been motivated to test CMMs of SBL in determining their ability to remove milk stain, for example, in view of their high performance taught by Bott et al.

Claims 36-42, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sierkstra et al. in view of Bott et al.

The teachings of Sierkstra et al. and Bott et al. are outlined above.

Claim 36-38, 40, 41, 44 and 45 are included in this 103 rejection to the extent that they clearly encompass the methods with the limitations of claims 39 and 42. The

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particular embodiments of claims 39 and 42 are not anticipated although as discussed above, claims 36-38, 40, 41, 44 and 45 also embrace embodiments which are anticipated. Thus both the 102 and 103 rejections are proper.

Bott et al. (WO 97/37007, form PTO-1449, reference B4) teach a CMM of SBL multimer wherein a residue at position 24 is replaced with cysteine and is attached to the next monomer using MTS. The dimer showed improved performance in the hydrolysis of skim milk or keratin (Example 3, Figures 2 and 3).

It would have been obvious to one of ordinary skill in the art at time the invention was made, to use a method disclosed by Sierkstra et al. with other protein stains such as blood and milk. It would have been further obvious to one of ordinary skill in the art at time the invention was made, to use other available SBL variants such as CMMs disclosed by Bott et al. in a method disclosed by Sierkstra et al. One of ordinary skill in the art at the time of filing would have been motivated to test CMMs of SBL in determining their ability to remove different protein stains such as milk, blood or grass stain, for example, in view of high performance of CMMs taught by Bott et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

August 19, 2003